UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE NEW ENGLAND COMPOUNDING PHARMACY, INC. PRODUCTS LIABILITY LITIGATION	)	MDL No. 2419
THIS DOCUMENT RELATES TO:	)	Dkt. No 1:13-md-2419 (FDS)
All Actions	)	

OBJECTION AND MOTION TO QUASH OF SURGERY CENTER ASSOCIATES OF HIGH POINT, LLC TO PLAINTIFFS' SUBPOENA TO TESTIFY AND TO PRODUCE DOCUMENTS

COMES NOW Respondent Surgery Center Associates of High Point, LLC ("Respondent"), by and through its counsel, and submits this Objection to the subpoena, dated June 21, 2013, issued to Respondent by the Plaintiffs Steering Committee ("Plaintiffs") in this Multi-District Litigation ("the subpoena"), a copy of which is attached hereto as "Exhibit 1." The subpoena should be quashed or modified pursuant to Federal Rules of Civil Procedure 45 and 26. In the alternative, the Court should issue a protective order pursuant to Federal Rule of Civil Procedure 26(c).

I. THE SUBPOENA SHOULD BE QUASHED BECAUSE RESPONDENT IS NOT THE PROPER PARTY.

On or about June 21, 2013, Plaintiffs served upon Surgery Center Associates of High Point, LLC, a subpoena ad testificandum, which was issued from the United States District Court for the District of Massachusetts and signed by attorney Patrick T. Fennell of Crandall & Katt of Roanoke, Virginia. The subpoena scheduled Respondent's deposition in High Point, North Carolina, on July 15, 2013, at 9:00 a.m.

The subpoena commands Respondent to designate corporate representatives to provide testimony and to produce documents as described in Exhibits A and B to the subpoena. Plaintiffs seek to compel testimony concerning 10 categories of designated subject matter and to compel the production of 21 categories of documents. The categories of deposition testimony sought all relate to the means by which the Respondent keeps, organizes, searches, retrieves and stores documents, in electronic and hard copy form, and means by which the Respondent will have obtained the documents sought by Exhibit B to the subpoena. The document production categories seek to determine whether and how New England Compounding Pharmacy, also known as the New England Compounding Center ("NECP") sold certain steroid medications to the Respondent, whether Respondent purchased those medications from sources other than NECP, to whom and when the medications were administered to Respondent's patients, the qualifications and fitness of NECP and its products and of compounding pharmacies in general, what insurance coverage is carried by Respondent, and Respondent's bylaws and corporate structure and ownership.

However, Respondent Surgery Center Associates of High Point, LLC, is not a health care provider, did not purchase any medications from NECP, and does not appear on the customer list for NECP that is published on the website of the Centers for Disease Control ("CDC"). It is a part owner of High Point Surgery Center, which is a licensed health care provider and is on the CDC's list, but the two entities are separate and distinct legal entities. The documents sought by the subpoena do not belong to Respondent and instead belong to High Point Surgery Center. As a result, Surgery Center Associates of High Point, LLC, is not a proper party to receive the subpoena and the subpoena should be quashed.

Additionally, the subpoena should be quashed because upon service, Plaintiffs failed to provide Respondent with the fee for one (1) day's attendance in violation of Rule 45(b)(1). Upon information and belief, Mr. Fennell is not licensed to practice law in North Carolina.

II. OBJECTIONS

Even if the Respondent were the proper recipient of the subpoena, the subpoena would be subject to multiple objections. Subject to and without waiving its objection and motion to quash for failure to name the proper entity above, Respondent Surgery Center Associates of High Point, LLC, also objects on the grounds that the subpoena has the following deficiencies:

- The subpoena exceeds the scope of the limited discovery approved by the Court.
- The subpoena creates an undue burden upon Respondent in violation of Federal Rules of Civil Procedure 26(b) and 45.
- The subpoena, the categories of documents sought, and the categories of testimony to be compelled at deposition are not reasonably calculated to lead to the discovery of admissible evidence.
- The subpoena seeks privileged information in violation of Federal Rule of Civil Procedure 45(c)(3)(A)(iii).
- The subpoena does not provide a reasonable period of time to comply in violation of Federal Rules of Civil Procedure 45(c)(3) and 34(b)(2)(A).
- Plaintiffs have breached their duty to take reasonable steps to avoid undue burden or expense in violation of Federal Rule of Civil Procedure 45(c)(1).

A. The Subpoena Exceeds the Scope of Discovery Allowed by the Court.

On June 21, this Court entered two Orders: (1) the "Order Granting Plaintiffs Leave to Serve Subpoenas and Qualified Protective Order Regarding Protection of Health Information"

(the "Subpoena and Qualified Protective Order") and (2) the "Order on Central Enforcement of Subpoenas" (the "Enforcement Order").

The first order, which allowed Plaintiffs to issue subpoenas, permitted Plaintiffs to issue subpoenas requesting specific types of individually identifiable health information and/or protected health information (collectively "PHI"), as those terms are defined under the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") and the regulations promulgated thereunder, from a limited time frame. Paragraph 2 of the Order states:

> The information requested and produced shall be limited to the names of patients that have been identified as receiving NECC solutions, medications or compounds from January, 2011 - November, 2012, the patients' last known address, the records identifying that NECC was the supplier of the solution, medication or compound, including lot number, the hospital or healthcare facilities' NECC product purchase records, including order forms, prescriptions, billing and accounts receivable, the hospital or healthcare facilities' NECC product storage and patient distribution records, and any other information that lead counsel and the PSC reasonably determine necessary to the prosecution and resolution of these actions.

Order Granting Plaintiffs Leave to Serve Subpoenas and Qualified Protective Order Regarding Protection of Health Information, MDL No. 2419, Master Dkt.: 1:13-md-02419-FDS, dated June 21, 2013, ¶ 2 (emphasis by underline added).

Although the Court's Order clearly limited Plaintiffs' authority to issue subpoenas, Plaintiffs requested that Respondent provide documents and things relating to PHI for a two-year period ending on October 6, 2012 (as well as additional documents and things going back for more than five and a half years from October 6, 2007 to the present). Even if they had named the proper entity, Plaintiffs have no authority to require production of documents and tangible things containing PHI for any time period other than the twenty-two month period from January 2011 until November 2012. Accordingly, all requests for PHI outside that time frame should be quashed.

B. Plaintiffs' Subpoena Attempts to Circumvent the Court's Requirement that Protected Health Information be Produced to a Vendor.

Plaintiffs' subpoena also violates the Court's Subpoena and Qualified Protective Order by requesting Respondent produce the documents containing PHI directly to Plaintiffs at the deposition. In the Subpoena and Qualified Protective Order, the Court explicitly stated that PHI shall be produced only to a third-party Vendor. *Id.*, ¶ 3. However, Exhibit B to the subpoena instead seeks to require Respondent to produce the documents directly to Plaintiffs'' counsel.

C. Plaintiffs Did Not Append the Subpoena and Qualified Protective Order to the Subpoenas.

In the Subpoena and Qualified Protective Order, the Court ordered: "A copy of this Order shall be appended to the subpoenas." *Id.*, ¶ 15. However, Plaintiffs did not append the Subpoena and Qualified Protective Order to the subpoena served upon but rather sent the order by separate cover days later.

D. Plaintiffs' Subpoena Places an Undue Burden on Respondent, and the Harm and Burden Imposed by the Subpoena Outweigh the Potential Need and Relevance of the Documents, Electronically Stored Information, and Tangible Things Requested.

When reviewing the enforcement of a subpoena sent to a nonparty such as Respondent, courts in the Middle District of North Carolina analyze the subpoena under both Rules 26 and 45 of the Federal Rules of Civil Procedure. In so doing, the court must "apply the balancing standards: relevance, need, confidentiality and harm. Even if the information sought is relevant, discovery is not allowed where no need is shown, or where compliance is unduly burdensome, or where the potential harm caused by production outweighs the benefit." *MacDermid Printing Solutions, L.L.C. v. E.I. Du Pont De Nemours & Co*., 1:10MC37, 2012 WL 734146 (M.D.N.C. Mar. 6, 2012) (citing *Insulate Am. v. Masco Corp*., 227 F.R.D. 427, 432 (W.D.N.C.2005)

(unpublished with copy attached hereto as "Exhibit 2"). Here, the potential relevance of and need for the documents and tangible things requested in Exhibit B to the subpoena are outweighed by the interest of confidentiality and the potential for harm posted by the requests. Even if it were the proper entity, compliance with Exhibit B to the subpoena, as written, is unduly burdensome, and the potential harm caused by the production outweighs the potential benefits.

First, Respondent is not a party to any case related to the fungal meningitis outbreak or any case that has been consolidated in the multi-district litigation ("MDL"). It does not have any documents that are relevant to the MDL or any protected health records of Plaintiffs. Even if it were properly identified in the subpoena, requiring the production of any documents other than the limited documents concerning the PHI of patients in the MDL during the time period allowed by this Court's Order would be an undue burden.

Second, many of the documents requested are easily obtained from other, more appropriate, sources. Plaintiffs requested numerous documents regarding the recall of NECP's medications that can be easily obtained from the FDA, CDC, or North Carolina Department of Health. (Subpoena, Exhibit B, Request Nos. 8, 9, 10.) Furthermore, the overwhelming majority of the documents requested can be easily produced by NECP, an actual party to the MDL. (*Id.*, Request Nos. 12, 13.) The fact that NECP's bankruptcy case and federal investigation may somehow delay Plaintiffs' discovery from NECP is no reason to burden a North Carolina entity who is not a party to this litigation.

Third, there is simply no need for many of the other documents sought. The document requests seek myriad information beyond just information about patients who may have received the steroid medications at issue during the time period at issue. Instead, the requests seek

documents, electronically stored information, and tangible things related to, *inter alia*, the purchase of certain medications from suppliers other than NECP, the administration of products purchased from NECP other than the steroid medications at issue during a time period longer than the twenty-two month period at issue, communications between the Respondent and any federal or state agency regarding the procurement of products from any compounding pharmacy, the Respondent's insurance policies, and the Respondent's bylaws and corporate structure. (*Id.*, Request Nos. 2, 3, 4, 5, 6, 10, 11.)

Fourth, many of the document requests are prohibitively overbroad, including the following:

> 2. Any and all documents and/or ESI reflecting, and/or related in any way whatsoever to, the procurement of MPA, or its generic or name-brand equivalent, from any producer, compounding facility or manufacturer other than NECP, since October 6, 2007, including without limitation of the foregoing, information reflecting dates of shipment and/or receipt, quantities of shipment, lot numbers and other identifying labels, sizes of containers of the product, the cost you paid for the product, applicable warranties, shelf life, expiration dates, requirements and instructions for shipment and/or storage, and the specific identity of the preparation being purchased.
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> 6. Any and all documents and/or ESI reflecting, and/or related to, the identification of each and every patient that was administered an NECP product during the two-year period immediately preceding October 6, 2012, including patient name, address, date of birth and identification of product administered.
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> 7. Any and all documents and/or ESI reflecting, or containing communications (written or otherwise) between Surgery Center Associates of High Point, LLC ("Healthcare Provider"), its employees, principals, partners, and/or agents, and NECP, its employees and/or agents during two-year period immediately preceding October 6, 2012….
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> 8. Any and all documents and/or ESI reflecting or containing information obtained by the Healthcare Provider, its employees and/or agents, regarding NECP…
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> 10. Any and all documents and/or ESI reflecting or containing information obtained by, or sent to, the Healthcare Provider, its employees and/agents, from the Centers for Disease Control and Prevention, the Federal

Food and Drug Administration, and/or any other Federal, state or local regulatory agency, concerning the fitness of any products manufactured, compounded or produced by NECP for their intended purposes.

11. Any and all documents and/or ESI reflecting or containing communications between the Healthcare Provider and any federal or state agency (including, but not limited to state licensing authorities, the Food and Drug Administration, and the Centers for Disease Control and Prevention) in connection with the procurement of products from any compounding pharmacy.

15. Any and all documents and/or ESI reflecting or containing communications made or issued by the Healthcare Provider, its employees and/or agents, in response to any recall notice regarding NECP products, including without limitation of the foregoing, the date, time and manner of transmission of the communication, the person(s) to which the communication was directed, and the person at the Healthcare Provider who made or delivered the communication.

18. Any and all policies of insurance, including without limitation of the foregoing, professional liability, malpractice, products liability, general liability, and comprehensive or umbrella policies, issued to the Healthcare Provider and/or its principal officers and directors and/or any physician working for or on behalf of the Healthcare provider, for the policy periods including calendar years 2011, 2012, and 2013.

19. Any and all documents and/or ESI reflecting or containing the names, addresses and positions (President, Vice-President, Director, etc.) within the Healthcare Provider of all officers and directors of the Healthcare Provider during the calendar years 2011, 2012 and 2013.

20. Any and all documents showing the entities or individuals with an ownership interest in the Healthcare Provider.

21. Any and all organizational charts maintained by the Healthcare Provider and/or documents listing directors, officers, employees, and/or agents of Healthcare Provider showing the names and positions of said directors, officers, employees, and/or agents and their relationship or rank within the Healthcare Provider.

(*Id.*, Request Nos. 2, 6, 7, 8, 10, 11, 15, 18, 19, 20, 21.) These requests seek wholesale categories of documents, electronically stored information, and tangible things that have no bearing on the matters at issue in the MDL without any meaningful limitation or other attempt to connect the requests to any fact of consequence.

Fifth, Plaintiffs' requests fail to seek information during the relevant period of the outbreak and the relevant period of the Court's Subpoena and Qualified Protective Order. The outbreak involved medications that were manufactured by NECP from May through August 2012. The requests are also not limited to the timeframe set by the Court: January, 2011 - November, 2012. Instead, Plaintiffs used arbitrary two and five year time periods without having any basis for such burdensome timeframes.

Sixth, the documents are broadly requested. Plaintiffs have failed to even name Respondent in several of the requests, instead referring to "Healthcare Provider." The requests are not specific as evidenced by the overlap of several requests, and the requests appear to have been sent to parties and non-parties alike, with no concern for the impropriety of treating a non-party like a party. More importantly, Plaintiffs' requests are burdensomely broad, and complying with them would require Respondent, a nonparty, to expend immense time and resources would require immense time and resources.

E. Plaintiffs Seek Privileged Information in Violation of Fed. R. Civ. P. 45(c)(3)(A)(iii).

To the extent that Plaintiffs' requests exceed the limitations set by the Subpoena and Qualified Protective Order, many of the requests in the subpoena also seek information that is protected by the attorney-client privilege and the work-product doctrine. Pursuant to Fed. R. Civ. P. 45(c)(3)(A)(iii), the court must quash or modify Plaintiffs' subpoena to the extent that it seeks privileged information.

II. CONCLUSION

For these reasons, Respondent Surgery Center Associates of High Point, LLC objects to and moves to quash the subpoena issued to it by Plaintiffs.

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CERTIFICATE OF SERVICE

This will certify that a true and accurate copy of the foregoing was served on all parties hereto by virtue of the Court's electronic filing system this 8th day of July, 2013.

/s/ Terrill J. Harris
Terrill Johnson Harris
Attorney for Surgery Center Associates of High Point, LLC